

REMARKS

Claims 25, 30-32 and 34 are pending. Claims 26, 28 and 29 have been canceled.

Claim Rejections under 35 U.S.C. § 103

Claims 25, 30-32 and 34 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Hunter et. al. (hereinafter “Hunter”) (U.S. Pat. No. 5,886,026). Applicants traverse.

Claim 25 is directed to a drug-loaded particle formulation method resulting in a coated a stent. The method includes adding polymeric particles containing a therapeutic substance to a fluid form of a stent coating material, wherein the coating material includes a polymeric material dissolved in a solvent and wherein the polymeric particles containing the therapeutic substance are suspended in the polymeric material dissolved in the solvent.

Hunter teaches compositions comprising an anti-angiogenic factor and a polymeric carrier. The Examiner admits on page 5 of the Office Action dated March 27, 2009, that Hunter discloses in Example 9 a process for manufacture of a stent coating, including the following step: “[a]n appropriate amount of paclitaxel is added to the solution and dissolved by hand shaking.”

In Example 9 in col. 48, Hunter teaches that after dissolving a polymer in dichloromethane (DCM), “a suitable volume (minimum 5 ml) of the 2% polymer solution is transferred to a separate 20 ml glass scintillation vial. The appropriate amount of paclitaxel is then added to the solution and dissolved by hand shaking.” (Hunter, col. 48, lines 6-9) (emphasis added). Futher, in the same Example, Hunter discloses “[u]sing a glass Pasteur pipette, dissolve the paclitaxel by gently pumping the polymer solution. Once the paclitaxel is dissolved, hold the test tube near the horizontal position.” *Id.* at lines 41-44.

This is contrary to the method in claim 25, wherein the polymeric particles containing the therapeutic substance are suspended in the polymeric material dissolved in the solvent.

The Examiner has not established a *prima facie* case of obviousness with respect to claim 35 because all of the elements have not been addressed and the cited prior art does not teach or suggest those elements. In the sections cited by the Examiner, the prior art teaches dissolving a therapeutic substance in a carrier polymer and coating the resulting solution on the stent, rather than creating a suspension of the therapeutic substance and a polymer, and coating the suspended therapeutic substance on the stent.

Therefore, claim 25 is not obvious under Hunter because the Examiner has not established a *prima facie* case. Claims 30-32 and 34 depend from claim 25, and are also not obvious under Hunter for the same reasons.

For all the above reasons, claim 25, and claims 30-32 and 34 dependent thereon, are allowable. Reconsideration and withdrawal of the rejections are respectfully requested.

CONCLUSION

The undersigned authorizes the Examiner to charge any fees that may be required or credit of any overpayment to be made to Deposit Account No. **07-1850**.

Should the Examiner have any questions regarding this communication, the Examiner is invited to contact the undersigned at the telephone number shown below.

Respectfully submitted,

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/RPA/

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